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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,202	07/23/2003	Carl Gustav Figdor	ALXN-P02-089	1242

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ROPES & GRAY LLP
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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
03/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,202	FIGDOR ET AL.	
	Examiner	Art Unit	
	MYRON G. HILL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7,19 and 23-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7,19 and 23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/5/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/5/08 has been entered.

Claims 1,3,4,6,7, 19 and 23-27 are under consideration.

IDS

A signed and initialed copy of the IDS filed 12/5/08 is enclosed.

Rejections Withdrawn

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3,4,6,7, 19 and 23-26 were rejected under 35 U.S.C. 102(b) as being anticipated by Curtis (WO93/01820).

After further consideration the rejection is withdrawn.

Rejections Necessitated By Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3,4,6,7,9, 19 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that the claims have been amended to recite reiterate reducing immune response, and that animal is not infected with HIV thus defining a specific population, that they have demonstrated that antibody to SEQ ID#2 reduces immune response, argues that in vitro is predictive of in vitro events with some cited art, and that the art cited by the examiner for unpredictability is directed at HIV and the instant claims are not directed to HIV treatments.

Applicant's arguments have been fully considered and not found persuasive.

> [0070] The invention further relates to a method for the prevention or treatment of HIV infections, comprising administering to a HIV infected patient or a person at risk of becoming HIV infected, a compound that can binds or bind to a C-type lectin on the surface of a dendritic cell, in such an amount that the adhesion of HIV to the dendritic cells, and in particular of the gp120 envelop protein of HIV to the C-type lectin on the surface of dendritic cells, is inhibited.

As can be seen from the support pointed to by applicant for "not infected" with HIV (paragraph 70), is in the context of "at risk of becoming HIV infected" and the method, like the method in the claims, is to binding a C type lectin on a dendritic cell thus blocking GP120 binding. While "not infected" is not literally supported, support is found and it is in the context of treating or preventing HIV.

Applicant's argument that the claims have been amended to define a specific population is not persuasive.

Applicant's citation of Jansen v Rexall is not sufficient to define a population as argued by applicant. The "in need thereof" in the cited case law is used in the context of the exemplified claims 1 and 4, and they are not analogous the pending claims. The claims from the case law recite a condition, anemia, and a cause, a deficiency in folic acid or vitamin B12 in a method of treating a patient in need thereof. The pending claims give no such guidance in determining the population and only include not HIV infected.

Applicants art for correlation (provided now on IDS) do not show in vivo correlation in the same scope as the claims. In Ingulli et al., the lymph nodes are removed to study cell interaction. There is no showing of any immune response.

The specification provides no guidance regarding practice of the claimed method. The amount of direction is limited to a cell culture assay to determine the effects of AZD-1 and AZD-2 in binding to SEQ ID# 2 and the reaction of that complex with other cell types (spec. pages 27-28).

Applicant points to paragraph 100 of the PG Pub and Figures 2 a and 2c to show support foe reducing immune response. These pertain to the making of antibodies that bind to ICAM-3, not to any function in immune response.

There is no evidence that shows any correlation with *in vivo* efficacy in the treatment or prevention of HIV or any other disease. *In vitro* testing is, at most, useful tool for screening but is not predictive of *in vivo* effectiveness. One skilled in the art would not associate successful *in vitro* testing results with successful *in vivo* treatment due to the high level of unpredictability of this art.

As pointed to above, the claims in light of the support found in paragraph 70 is for at risk of HIV infection and the method is to treating or preventing HIV.

The results in the specification or those shown in the art provided do not show the reduction of immune response in mammals by an antibody that binds to SEQ ID# 2.

The rejection is maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M,W,F, and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. H./
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648